
TITLE 345 INDIANA STATE BOARD OF ANIMAL HEALTH

Proposed Rule
LSA Document #13-230

DIGEST

Adds [345 IAC 9-2-3](#) to clarify that an establishment that produces non-intact beef products is required to conduct microbiological testing as a component of the ongoing verification activities required by 9 CFR 417.4. Amends [345 IAC 9-2.1-1](#) and [345 IAC 10-2.1-1](#) to change the incorporation by reference from January 1, 2012, to January 1, 2013. Amends [345 IAC 9-17-4](#) to require an establishment selected for the USDA-FSIS Cooperative Program for Interstate Shipment of Carcasses, Parts of Carcasses, Meat and Meat Food Products to comply with the labeling requirements at 9 CFR Part 317. *NOTE: LSA Document #13-230, posted at [20130828-IR-345130230PRA](#), was revised and resubmitted for publication.* Effective 30 days after filing with the Publisher.

[IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses](#)[345 IAC 9-2-3](#); [345 IAC 9-2.1-1](#); [345 IAC 9-17-4](#); [345 IAC 10-2.1-1](#)

SECTION 1. [345 IAC 9-2-3](#) IS ADDED TO READ AS FOLLOWS:

[345 IAC 9-2-3](#) Verification of HACCP systems

Authority: [IC 15-17](#)

Affected: [IC 15-17](#)

Sec. 3. (a) Every establishment must conduct validation, verification, and reassessment activities pursuant to 9 CFR 417.4 to support that the HACCP system is designed and functioning as intended on an ongoing basis.

(b) An establishment that:

(1) produces a non-intact beef product; and

(2) pursuant to 9 CFR 417.2, has determined that contamination with Shiga toxin-producing *Escherichia coli* (STEC) is a food safety hazard reasonably likely to occur;

must include microbiological testing as a component of their ongoing verification activities. The testing must demonstrate that the HACCP system is effectively preventing this identified hazard. The microbiological testing frequency for an establishment will be determined by the board based upon the volume of product produced, the type of product produced, the establishment's compliance history, and any other factors affecting the risk that the pathogen is in the product.

(Indiana State Board of Animal Health; [345 IAC 9-2-3](#))

SECTION 2. [345 IAC 9-2.1-1](#) IS AMENDED TO READ AS FOLLOWS:

[345 IAC 9-2.1-1](#) Incorporation by reference

Authority: [IC 15-17](#)

Affected: [IC 4-21.5-3](#); [IC 15-17-2](#); [IC 15-17-17](#)

Sec. 1. (a) The board adopts as its rule and incorporates by reference the following federal regulations in effect on January 1, 2012: **2013:**

(1) 9 CFR 301, except the definitions in [IC 15-17-2](#) and [345 IAC 9-1-3](#) shall control over conflicting definitions in 9 CFR.

(2) 9 CFR 303 through 9 CFR 311, except the following are not incorporated:

(A) 9 CFR 303.1(c), 9 CFR 303.1(g), and 9 CFR 303.2.

(B) 9 CFR 306.1.

(C) 9 CFR 307.4, 9 CFR 307.5, and 9 CFR 307.6.

(D) 9 CFR 308.

(3) 9 CFR 313 through 9 CFR 320, except 9 CFR 317.4 and 9 CFR 317.5.

(4) 9 CFR 325.

(5) 9 CFR 416 through 9 CFR 441.

(6) 9 CFR 500, except the following:

(A) References to the Uniform Rules of Practice, 7 CFR Subtitle A, Part 1, Subpart H, shall mean [IC 15-17-17](#) and [IC 4-21.5-3](#).

(B) References to adulterated or misbranded product shall refer to products adulterated or misbranded as defined in [IC 15-17-2](#).

(b) When interpreting this article, including all matters incorporated by reference, the following shall apply:

(1) A reference to any subpart of 9 CFR 302 refers to the corresponding section of [345 IAC 9-2](#).

(2) A reference to:

(A) 9 CFR 307.4 shall refer to [345 IAC 9-7-4](#);

(B) 9 CFR 307.5 shall refer to [345 IAC 9-7-6](#); and

(C) 9 CFR 307.6 shall refer to [345 IAC 9-7-6](#).

(3) A reference to any subpart of 9 CFR 312 refers to the corresponding section of [345 IAC 9-12](#).

(4) A reference to:

(A) 9 CFR 316.16 shall refer to [345 IAC 9-16-16](#);

(B) 9 CFR 317.4 shall refer to [345 IAC 9-17-4](#);

(C) 9 CFR 317.5 shall refer to [345 IAC 9-17-5](#); and

(D) 9 CFR 317.16 shall refer to [345 IAC 9-17-16](#).

(5) A reference to:

(A) 9 CFR 321.1 shall refer to [345 IAC 9-20](#); and

(B) 9 CFR 321.2 shall refer to [345 IAC 9-20](#).

(6) A reference to any subpart of 9 CFR 329 shall refer to the corresponding section in [345 IAC 9-22](#).

(c) Where the provisions of this article conflict with matters incorporated by reference, the express provisions of this article shall control.

(d) The board will utilize the latest edition of the following documents issued by the United States Department of Agriculture when interpreting and implementing the provisions of this article and [IC 15-17](#):

(1) Food Safety and Inspection Service Regulatory Directives.

(2) Food Safety and Inspection Service Notices.

(e) Copies of incorporated documents and interpreting and implementing documents may be obtained from the United States Department of Agriculture, Food Safety Inspection Service website, the U.S. Government Printing Office website, or by sending a written request to the board.

(Indiana State Board of Animal Health; [345 IAC 9-2.1-1](#); filed Dec 10, 1997, 11:30 a.m.: 21 IR 1301; filed Sep 10, 1999, 9:14 a.m.: 23 IR 14; filed Oct 30, 2000, 2:06 p.m.: 24 IR 678; readopted filed May 2, 2001, 1:45 p.m.: 24 IR 2895; filed Dec 19, 2002, 12:43 p.m.: 26 IR 1540; filed Jul 14, 2004, 9:25 a.m.: 27 IR 3982; filed Jan 5, 2006, 8:00 a.m.: 29 IR 1552; readopted filed May 9, 2007, 3:16 p.m.: [20070516-IR-345070037RFA](#); filed Aug 11, 2008, 3:39 p.m.: [20080910-IR-345080126FRA](#); errata filed Oct 3, 2008, 3:30 p.m.: [20081022-IR-345080767ACA](#); filed Nov 24, 2010, 3:20 p.m.: [20101222-IR-345100122FRA](#); filed Sep 18, 2012, 2:21 p.m.: [20121017-IR-345120108FRA](#))

SECTION 3. [345 IAC 9-17-4](#) IS AMENDED TO READ AS FOLLOWS:

[345 IAC 9-17-4](#) Submission of labels for approval

Authority: [IC 15-17](#)

Affected: [IC 15-17-5](#)

Sec. 4. (a) **Notwithstanding any provision of this rule, labels for products to be shipped interstate by an establishment that is a selected establishment under 9 CFR Part 332 shall comply with the requirements for participation in the interstate shipment program, such as label approval under 9 CFR Part 317.** Except as provided in subsection (d), no label shall be used on any product until it has been approved in its final form by the board. For the convenience of the establishment, sketches or proofs of new labels may be submitted in triplicate through the officer in charge to the division for approval and the preparation of finished labels deferred until such approval is obtained. All finished labels shall be submitted in triplicate through the officer in charge to the division for approval.

(b) In case of lithographed labels, paper take-offs in lieu of sections of the metal containers shall be submitted for approval. Such paper take-offs shall be in the form of a negative but shall be a complete reproduction of the label as it will appear on the package, including any color scheme involved. In case of fiber containers, printed layers, such as the kraft paper sheet, shall be submitted for approval in lieu of the complete container.

(c) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within, containers and coverings of product shall be submitted for approval in the same manner as provided for labels in subsection (a), except that officers in charge may permit use of such devices that contain no reference to product and bear no misleading feature.

(d) Stencils, labels, box dies, and brands may be used on shipping containers and on such immediate containers as tierces, barrels, drums, boxes, crates, and large-size fiberboard containers, provided the markings are **as follows:**

- (1) Applicable to the product. ~~are~~
- (2) Not false or deceptive. ~~and are~~
- (3) Used with the approval of the officer in charge.

The inspection legend for use in combination with such markings shall be approved by the board.

(Indiana State Board of Animal Health; Reg HMP-1R, CH A, PT 18, Sec 19-4; filed Feb 11, 1972, 2:00 p.m.: Rules and Regs. 1973, p. 313; filed Aug 13, 1973, 9:20 a.m.: Rules and Regs. 1974, p. 238; filed Jan 8, 1982, 10:42 a.m.: 5 IR 362; filed Dec 10, 1997, 11:30 a.m.: 21 IR 1307; readopted filed May 2, 2001, 1:45 p.m.: 24 IR 2895; readopted filed May 9, 2007, 3:16 p.m.: [20070516-IR-345070037RFA](#); readopted filed Aug 7, 2013, 8:32 a.m.: [20130904-IR-345130236RFA](#)) NOTE: Transferred from the Indiana State Department of Health ([410 IAC 9-17-4](#)) to the Indiana State Board of Animal Health ([345 IAC 9-17-4](#)) by P.L.137-1996, SECTION 76, effective July 1, 1996.

SECTION 4. [345 IAC 10-2.1-1](#) IS AMENDED TO READ AS FOLLOWS:

[345 IAC 10-2.1-1](#) Incorporation by reference; poultry products inspection

Authority: [IC 15-17](#)

Affected: [IC 4-21.5-3](#); [IC 15-17](#)

Sec. 1. (a) The board adopts as its rule and incorporates by reference the following federal regulations in effect on January 1, ~~2012~~: **2013**:

- (1) 9 CFR Part 362 with the following amendments and additions:
 - (A) 9 CFR 362.4(a)(2), 9 CFR 362.4(b)(2), 9 CFR 362.4(c), 9 CFR 362.4(d), and 9 CFR 362.5 are not incorporated.
 - (B) Fees for voluntary inspection service shall be charged in accordance with [IC 15-17-5-12](#).
 - (C) The state veterinarian may refuse to provide or withdraw voluntary inspection service for administrative reasons, including nonavailability of personnel and failure to pay for service.
- (2) 9 CFR 381.1, except the definitions in [IC 15-17](#) and [345 IAC 10-1-1](#) shall control over conflicting definitions in 9 CFR.
- (3) 9 CFR 381.10 with the following amendments and additions:
 - (A) 9 CFR 381.10(d)(2)(i) shall be amended by deleting the word "unless" and the remaining part of the sentence that follows that word.
 - (B) A person operating a facility engaged in exempt operations described in 9 CFR 381.10(a)(4) through 9 CFR 381.10(a)(7) and 9 CFR 381.10(b) through 9 CFR 381.10(c) shall comply with the registration and record keeping requirements in 9 CFR 381.175 through 9 CFR 381.182.
- (4) 9 CFR 381.11 through 9 CFR 381.95, except the following are not incorporated:
 - (A) 9 CFR 381.36.
 - (B) 9 CFR 381.37.
 - (C) 9 CFR 381.38.
 - (D) 9 CFR 381.39.
- (5) 9 CFR 381.115 through 9 CFR 381.182, except the following are not incorporated:
 - (A) 9 CFR 381.132.
 - (B) 9 CFR 381.133.
- (6) 9 CFR 381.189 through 9 CFR 381.194.
- (7) 9 CFR 381.300 through 9 CFR 381.500.

(8) 9 CFR 416 through 9 CFR 441.

(9) 9 CFR 500, except the following:

(A) References to Uniform Rules of Practice, 7 CFR Subtitle A, Part 1, Subpart H shall mean [IC 15-17-17](#) and [IC 4-21.5-3](#).

(B) References to adulterated or misbranded product shall refer to products adulterated or misbranded as defined in [IC 15-17-2](#).

(b) When interpreting this article, including all matters incorporated by reference, the following shall apply:

(1) References to 9 CFR 381.3 through 9 CFR 381.7 refer to the corresponding section in [345 IAC 10-2](#).

(2) References to:

(A) 9 CFR 381.36 refer to [345 IAC 10-7-1](#);

(B) 9 CFR 381.37 refer to [345 IAC 10-7-2](#) and [345 IAC 10-7-3](#); and

(C) 9 CFR 381.38 and 9 CFR 381.39 refer to [345 IAC 10-7-4](#).

(3) References to:

(A) 9 CFR 381.96 refer to [345 IAC 10-13-1](#);

(B) 9 CFR 381.98 refer to [345 IAC 10-13-2](#);

(C) 9 CFR 381.99 refer to [345 IAC 10-13-3](#);

(D) 9 CFR 381.100 refer to [345 IAC 10-13-4](#);

(E) 9 CFR 381.101 refer to [345 IAC 10-13-5](#);

(F) 9 CFR 381.103 refer to [345 IAC 10-13-6](#);

(G) 9 CFR 381.110 refer to [345 IAC 10-13-7](#); and

(H) 9 CFR 381.111 refer to [345 IAC 10-13-8](#).

(4) References to 9 CFR 381.131, 9 CFR 381.132, and 9 CFR 381.133 refer to [345 IAC 10-14-18](#) and [345 IAC 10-14-20](#).

(5) References to:

(A) 9 CFR 381.185 refer to [345 IAC 10-18-1](#); and

(B) 9 CFR 381.186 refer to [345 IAC 10-18-2](#).

(6) References to 9 CFR 381.210 through 9 CFR 381.218 refer to the corresponding section of [345 IAC 10-20](#).

(c) Where the provisions of this article conflict with matters incorporated by reference, the express provisions of this article shall control.

(Indiana State Board of Animal Health; [345 IAC 10-2.1-1](#); filed Dec 10, 1997, 11:30 a.m.: 21 IR 1319; errata filed Mar 9, 1998, 9:30 a.m.: 21 IR 2393; filed Sep 10, 1999, 9:14 a.m.: 23 IR 16; filed Oct 30, 2000, 2:06 p.m.: 24 IR 685; errata filed Apr 9, 2001, 12:52 p.m.: 24 IR 2470; readopted filed May 2, 2001, 1:45 p.m.: 24 IR 2895; filed Dec 19, 2002, 12:43 p.m.: 26 IR 1541; filed Dec 16, 2004, 1:30 p.m.: 28 IR 1474; filed Jan 5, 2006, 8:00 a.m.: 29 IR 1554; readopted filed May 9, 2007, 3:16 p.m.: [20070516-IR-345070037RFA](#); filed Aug 11, 2008, 3:39 p.m.: [20080910-IR-345080126FRA](#); errata filed Oct 3, 2008, 3:30 p.m.: [20081022-IR-345080767ACA](#); filed Nov 24, 2010, 3:20 p.m.: [20101222-IR-345100122FRA](#); filed Sep 18, 2012, 2:21 p.m.: [20121017-IR-345120108FRA](#))

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